STA-MED, LLC
41197 Golden Gate Circle, Suite 102
Murrieta, CA 92562

Attachment 2 – 510(k) Summary

5. 510(k) Summary

APR - 6 2010

STA-MED, LLC.
41197 Golden Gate Circle, Suite 102
Murrieta, CA 92562

SUMMARY

Submitter's name:	STA-MED, LLC.
Address:	41197 Golden Gate Circle, Suite 102 Murrieta, CA 92562
Phone:	951-445-4601
Fax number:	951-445-4602
Name of contact person:	Greg Holland Regulatory Specialists, Inc 3722 Ave. Sausalito Irvine, CA 92606 Phone: 949-262-0411 greg@regulatoryspecialists.com
Name of the device:	Med-Lok, Safety Needle
Classification name:	Piston Syringe
Product code	MEG
Device Class	Class 2
Date	December 21, 2009

The legally marketed device to which we are claiming equivalence [807.92(a)(3)]:

Reference #	Device Name	Applicant
K063755	Portex Hypodermic Needle-Pro	SMITHS MEDICAL ASD, INC

Description of the device:

The Med-Lok is a hypodermic needle with protection device that allows full use of the needle and covers the needle after use to help prevent needle sticks and touch contamination.

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Indications:

The Med-Lok Safety Needle Device is intended for aspirations and injections of fluids. The needle protection device covers the needle after use to help prevent needle sticks.

Summary of the technological characteristics of our device compared to the predicate device:

Technological Characteristics

This proposed device has the same technological characteristics as the predicate device.

Indications for Use

The Indications for Use for this proposed device has the same Indications for Use as the predicate device.

Performance Testing

Testing was performed to demonstrate the product functions as intended and is shown to be substantially equivalent. These tests included extensive laboratory testing.

Clinical Testing

Simulated clinical use studies were conducted which confirmed that the device could be used effectively with the needle shielded inside the protection device after use.

CONCLUSION

Based on the design, technology, performance, functional testing, and intended use, the Med-Lok, Safety Needle is substantially equivalent to the predicate devices currently marketed under the Federal Food, Drug and Cosmetic Act. The Med-Lok, Safety Needle raises no new issues of safety or effectiveness. Therefore, safety and effectiveness are reasonably assured, and substantial equivalence is supported, justifying 510(k) clearance of Med-Lok, Safety Needle.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

STA-MED, LLC
C/O Mr. Greg Holland
Regulatory Consultant
Regulatory Specialist, Incorporated
3722 Avenue Sausalito
Irvine, California 92606

APR - 6 2010

Re: K093176
Trade/Device Name: Med-Lok
Regulation Number: 21CFR 880.5860
Regulation Name: Piston Syringe
Regulatory Class: II
Product Code: MEG
Dated: March 19, 2010
Received: March 23, 2010

Dear Mr. Holland:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

STA-MED, LLC
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Attachment 1 – Revised Indications for Use Statement.

4. Indications for Use Statement

Indications for Use

510(k) Number (if known): K093176

Device Name: Med-Lok

Indications for Use: The Med-Lok™ Safety Needle Device is intended for aspirations and injections of fluids. The needle protection device covers the needle after use to help prevent needle sticks.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K093176

Page 1 of 1